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Jane A. Axelrod 12/7/04
Associate Director of Policy
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857-0001

Re: Docket No. 2003P-0531

Dear Ms. Axelrod,

I am writing to inquire about the current status of our petition and to provide the FDA with some current information which is pertinent to the petition.

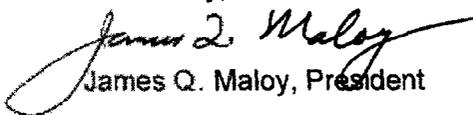
The 2004 edition of Handbook 44, published by NIST, which sets forth the Specifications, Tolerances, and other Technical Requirements for Weighing and Measuring Devices has made legal the technique of estimating the count of pills in filling a prescription in a pharmacy. This exception to the total ban on estimating count by weight in commerce was allowed on the basis that pill weights have tight Pill Weight tolerances which are controlled by the FDA. In fact, the Dosage Weight (equals weight of the active ingredient) is held to tight tolerances (as they should be), while the Pill Weight (equals dosage weight plus excipients weight) is held to loose tolerances in order that the Dosage Weight may be tightly controlled within a given batch of pills. The Pill Weight is usually much larger than the Dosage weight and far less controlled (see U.S. Pharmacopeia, Chapter- Uniformity of Dosage Units (Section 905, USP 24-NF 19 Supplement, July 1, 2000, pages 2094 to 2096)

These loose Pill Weight tolerances can lead to serious counting errors when a scale is used to count the pills on the basis of an average pill weight (stored in memory) and based upon the weight of pills from the same or another production lot.

The NTEP has issued Certificates of Conformance for several scales (see the enclosed sample). Scales are now being marketed and sold for use in pharmacies.

We believe that counting pills by weight is inaccurate, and that the FDA, which oversees and regulates the manufacturing of these pills, has, and can provide, the necessary information to allow the NIST and National Conference on Weights and Measures (NCWM) to reach an informed decision on this matter.

Yours truly,


James Q. Maloy, President

2003P-0531

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National Conference on Weights and Measures
15245 Shady Grove Road, Suite 130 • Rockville, MD 20850

Certificate Number: 04-077P
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National Type Evaluation Program
Certificate of Conformance
for Weighing and Measuring Devices

For:

Non-Computing Scale, prescription, counting
Digital Electronic
Model: GF-P Series
 n_{max} and e_{min} : (See Table on Page 2)
Platform: See Table on Page 2

Accuracy Class: II

Submitted by:

A&D Engineering
1555 McCandless Drive
Milpitas, CA 95035
Tel: (408) 263-5333
Fax: (408) 263-0119
Contact: Jesus Zapien

Standard Features and Options

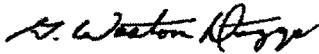
The GF Series has the following externally selectable units of measure using the "mode" push-button:
gram (g), ounce (oz), pound (lb), troy ounce (ozt).

"The counting feature for prescription filling only", is labeled on the front of the scale
Counting and percent weighing
Semi-automatic zero setting mechanism (push-button)
Automatic zero setting mechanism (AZSM)
Initial zero setting mechanism (IZSM)
RS-232 serial interface
AC/DC adapter
Level indicator
Motion annunciator
Vacuum fluorescent display
Weight comparator mode

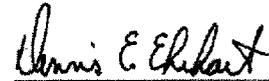
Load cell used: A&D Mode 2000468 (non-NTEP approved)

Temperature Range: 5 °C to 30 °C (41 °F to 86 °F)

This device was evaluated under the National Type Evaluation Program (NTEP) and was found to comply with the applicable technical requirements of Handbook 44, "Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices." Evaluation results and device characteristics necessary for inspection and use in commerce are on the following pages.



G. Weston Diggs
Chairman, NCWM, Inc.



Dennis E. Ehrhart
Chairman, National Type Evaluation Program Committee
Issue date: August 12, 2004

Note: The National Conference on Weights and Measures does not "approve", "recommend", or "endorse" any proprietary product or material, either as a single item or as a class or group. Results shall not be used in advertising or sales promotion to indicate explicit or implicit endorsement of the product or material by the NCWM.

A&D Engineering
Bench Scale, Top Loading Balance, Prescription Balance
Model: GF-P Series

Application: General purpose top loading balance, prescription weighing and counting. Counting feature for prescription filling.

Identification: The manufacturer's identification, model number, and serial number are on a pressure sensitive, self-destructive label located on the right side of the scale.

Model	Capacity (g)	n_{max}	e (g)	d (g)	Platform (mm)
GF-200P	210	21 000	0.01	0.001	128 x 128
GF-300P	310	31 000	0.01	0.001	128 x 128
GF-1200P	1 210	12 100	0.1	0.01	165 x 165
GF-2000P	2 100	21 000	0.1	0.01	165 x 165
GF-3000P	3 100	31 000	0.1	0.01	165 x 165
GF-6000P	6 100	6 100	1	0.1	165 x 165

Sealing: The device can be sealed by threading a wire security seal through the RS-232 serial interface plate and scale housing. A switch located on the RS-232 serial interface printed circuit board allows access to calibration and configuration mode.

Test Conditions: A GF-300 and GF-3000 were submitted for evaluation. The emphasis of the evaluation was on device design and performance for prescription counting. With the exception that the software has been updated to do prescription weighing there is no differences in these devices than the ones stated in Certificate of Conformance Number 03-005. Each scale was tested to verify performance and accuracy for the prescription criteria. The A&D Model GF-300P & 3000P, Class II prescription scales were evaluated using the ad-hoc procedure for the counting feature that was developed by the NTEP Labs for the Counting Feature for Prescription Filling.

This certificate is designated as "Provisional" because of the ad-hoc procedure used for the evaluation. When the procedure is finalized and incorporated into Publication 14, the provisional certificate will be upgraded to a full NTEP certificate.

Evaluated By: Todd Lucas (OH)

Type Evaluation Criteria Used: NIST Handbook 44, 2004 Edition; NCWM Publication 14, 2004 Edition

Conclusion: The results of the evaluation and information provided by the manufacturer indicate the devices comply with applicable requirements.

Information Reviewed By: S. Patoray, L. Bernetich (NCWM)

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Certificate Number: 96-116A3P

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National Type Evaluation Program Certificate of Conformance for Weighing and Measuring Devices

For:

Non-Computing Scale, Counter/Bench
Digital Electronic
Models: Universal 2000, Universal BU 2010 & AccuCount *
see page 2
 n_{max} : * See Table Below
 e_{min} : * See Table Below
Capacity: * See Table Below
Platform: 170 mm diameter
Accuracy Class: II

Submitted by:

McKesson APS
700 Waterfront Drive
Pittsburgh, PA 15222
Tel: 412-209-4098
Fax: 412-209-3930
Contact: Brian Christopher

Standard Features and Options

Model ID	Capacity	n_{max}	e_{min}
Universal 2000	310 grams	31 000	$e = 0.01$ g; $d = 0.001$ g
BU 2010	620 grams	62 000	$e = 0.01$ g; $d = 0.001$ g
AccuCount	620 grams	62 000	$e = 0.01$ g; $d = 0.001$ g

Automatic Zero setting mechanism (AZSM)
Initial zero setting mechanism (IZSM)
On/Off Re-Zero (SAZSM)
RS-232 connector

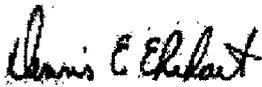
Push button tare
R_x Check button
Gross / Net display

Universal BU 2010 & AccuCount - The scale will be marked "For Prescription Weighing & Counting Only"
Universal BU 2010 & AccuCount - The scale will be marked "Min Pc Wt = 0.03g" & "Min Sample = 20 Pcs"

Note: All AccuCount™ scales version 1.0 and higher will have the listed markings. Only BU 2010s that received field upgrades to software version 3.0 or higher will have the listed markings. To determine the version number of the scale, turn power off, then back on and the version number of the software is displayed as the scale powers up.

Temperature Range: 10°C to 30 °C (50 °F to 86 °F)

This device was evaluated under the National Type Evaluation Program (NTEP) and was found to comply with the applicable technical requirements of Handbook 44, "Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices." Evaluation results and device characteristics necessary for inspection and use in commerce are on the following pages.



Dennis E. Ehrhart
Chairman, NCWM, Inc.



Ross J. Andersen
Chairman, National Type Evaluation Program Committee
Issued Date: February 17, 2004

Note: The National Conference on Weights and Measures does not "approve", "recommend", or "endorse" any proprietary product or material, either as a single item or as a class or group. Results shall not be used in advertising or sales promotion to indicate explicit or implicit endorsement of the product or material by the NCWM.

**McKesson APS
Bench Scale**

Models: Universal 2000, Universal BU 2010 & AccuCount

Application: For prescription weighing and counting only. Counting Feature for Prescription filling: The model Universal 2000 will not have a legal for trade counting feature. The model AccuCount will have the legal for trade counting feature for prescription filling only. The model BU 2010 will need to be retrofitted with updated software to have the legal for trade counting feature. When the BU 2010 is retrofitted, the markings will be updated to indicate that the scale has the legal for trade counting feature.

Identification: Universal 2000, Universal BU 2010 & AccuCount™; The Manufacturers name, model number, capacity by division, e_{min} and when applicable minimum piece weight and minimum sample size appears on the front of the scale adjacent to the weight display a white paper badge that repeats the word "VOID" when removed. The other required markings appear on a paper badge on the right side of the scale. The BU 2010 up-date markings (if applicable) "Prescription Weighing and Counting Only", minimum piece weight and minimum sample size will be marked on the front near the weight display on a white paper badge that repeats the word "VOID" when removed. The restricted temperature range is also stated in the operator's manual.

Sealing: Universal 2000; On the right side of the scale near the front are two drilled head screws. The bottom screw covers a hole, which allows access to the calibration and configuration push button. Passing a wire seal through the two drilled screw-heads seals the scale.

BU 2010 & AccuCount™; Located on the back of the device, two sealing methods are possible (or a combination of using both methods); (1) Two drilled head screws, one that secures the top and bottom sections of the device and the other drilled screw that when inserted into the hole (located just below the screw that secures the top and bottom pieces) will not allow access to the calibration button.

(2) With a screw already inserted into the calibration hole, a flat, tapered head screw with a long shaft that would extend down past the calibration access screw, thus not allowing it to be backed out. This flat, tapered screw when fully inserted can be sealed with a paper seal covering the head of the screw and onto the metal sides surrounding it.

Test Conditions: This Certificate Supersedes Certificate of Conformance Number 96-116A2 and is issued to add the Counting Feature for Prescription Filling and to change the name of the manufacturer. One McKesson Model AccuCount scale was submitted for evaluation with the 3.0 version software enabling the Counting Feature for Prescription Filling. Several increasing/decreasing load tests were performed to insure the scale was calibrated correctly and to determine that the scale still operated in the same manner as when it was previously evaluated. The counting Feature was evaluated using the ad-hoc procedure that was developed by the NTEP Labs for the Counting Feature for Prescription Filling. Previous test conditions are listed below as reference.

This certificate is designated as "Provisional" because of the ad-hoc procedure used for the evaluation. When the procedure is finalized and incorporated into Publication 14, the provisional certificate will be upgraded to a full NTEP certificate.

Certificate of Conformance Number 96-116A2: This Certificate Supersedes Certificate of Conformance Number 96-116A1 and is issued to correct information in the Standard Features and Options Box. No additional evaluation was required. Previous test conditions are listed below as reference.

Certificate of Conformance Number 96-116A1: This certificate supersedes Certificate Number 99-116 and is issued to add the Baker/APS model BU 2010. A Baker/APS model BU 2010, 620 x 0.01 gram Class II scale was submitted for the evaluation. The emphasis of the evaluation was on device design, operation, marking requirements and compliance with environmental factor requirements. Several increasing / decreasing load and shift tests were performed. The scale was tested with 100 VAC and 130 VAC power supplies. Tests were conducted over a range of temperature from 10° to 30°C (50 to 86°F). A load of approximately 1/2 capacity was applied to the scale 100 055 times. The scale was tested periodically over this time. The results of the evaluation indicate the device is capable of meeting the applicable requirements of NIST Handbook 44.

**McKesson APS
Bench Scale
Models: Universal 2000, Universal BU 2010 & AccuCount**

Test Conditions Continued:

Certificate of Conformance Number 96-116: A 310 x 0.01 gram scale was submitted for evaluation. The emphasis of the evaluation was on device design, operation, marking requirements and compliance with environmental factor requirements. Several increasing / decreasing load and shift tests were performed. The scale was tested with 100 VAC and 130 VAC power supplies. Tests were conducted over a range of temperature from 10 to 30°C (50 to 86°F). A load of approximately 1/2 capacity was applied to the scale 100 720 times. The scale was tested periodically over this time.

The results of the evaluations and information provided by the manufacturer indicate the devices comply with applicable requirements.

Type Evaluation Criteria Used: NIST Handbook 44, 2000 Edition; NIST Handbook 44, 2004 Edition 96-116A3P; NCWM Publication 14, 2003 Edition

Tested By: A. McCoy, (OH), W. West (OH) 96-116; T. Lucas (OH) 96-116A1& 96-116A3

Information Reviewed By: S. Patoray (NCWM), L. Bernetich (NCWM) 96-116A2, 96-116A3P